NxStage Medical, Inc.
NxStage® Streamline Express
510(k) Premarket Notification Submission

FEB - 4 201

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content contained in this 510(k) summary has been provided in conformance with 21 CFR §807.92

Date:

A. Date December 20, 2013

B. Submitter's Information:

Name:	NxStage Medical, Inc.
Address:	350 Merrimack Street Lawrence, MA 01843 United States
FDA Establishment Owner/Operator Number:	9045797
Contact Person:	Mary Lou Stroumbos Director, Regulatory Affairs
Phone:	(978) 687-4872
Fax:	(978) 687-4750
Manufacturing Site:	MEDIMEXICO, S. DE R.L. DE C.V. Av. Valle imperial No. 10523 Parque industrial Valle Sur Tijuana, B.C., Mexico 22180
FDA Establishment Registration Number:	9616074
Sterilization Site:	Steris Corporation Isomedix Services, Inc. 1000 S. Sarah Place Ontario, CA 91761
FDA Establishment Registration Number:	Contract sterilizer

C. Device Name:

Trade/Proprietary Name:	NxStage Streamline Express for Fresenius 2008 Series Hemodialysis Systems
Device:	Set, tubing, blood, with and without anti-regurgitation valve
Regulation Description:	Hemodialysis System and Accessories

NxStage Medical, Inc.
NxStage® Streamline Express
510(k) Premarket Notification Submission

Regulation Medical Specialty:	Gastroenterology/Urology Devices
Review Panel:	Gastroenterology/Urology
Product Code:	KDI FJK KOC
Submission Type:	510(k)
Regulation Number:	876.5860
Device Class:	II

D. Predicate Devices:

Streamline Airless System Set with Pre-Attached Dialyzer for B.Braun Dialog Series Hemodialysis Systems	**K113023**
Blood Tubing Sets	**K080807**
Reverso	**K994306**

E. Substantial Equivalence:

The proposed NxStage dialyzer with pre-attached blood tubing set is substantially equivalent to the identified predicates.

F. Device Description/Indications for Use:

The proposed device provides for the treatment of acute or chronic renal failure when used with the commercially available Fresenius 2008 Series hemodialysis systems. The device is a single use high flux (permeability) hollow-fiber dialyzer pre-attached to a blood tubing set.

Indications for use:

The single use dialyzer with pre-attached blood tubing set is indicated for use with the Fresenius 2008 Series hemodialysis systems for the treatment of acute and chronic renal failure.

G. Technological Characteristics:

The proposed device has the same technological characteristics and is similar in design and configuration as compared to the predicate devices.

NxStage Medical, Inc.
NxStage® Streamline Express
510(k) Premarket Notification Submission

Device Technological Characteristics Comparison Table		
Parameter	**Proposed Device Streamline Express for Fresenius 2008 Series Hemodialysis Systems**	**Predicate Device Streamline Airless System Set with Pre-Attached Dialyzer for B. Braun Dialog Series Hemodialysis Systems (K113023)**
Intended use	The single use dialyzer with pre-attached blood tubing set is indicated for use with the Fresenius 2008 Series Hemodialysis Systems for the treatment of acute and chronic renal failure.	The single use blood tubing set with pre-attached dialyzer is indicated for use with the B. Braun Dialog Series Hemodialysis Systems for the treatment of acute and chronic renal failure.
Principle of Operation	Removal of solutes via diffusion or convection	Removal of solutes via diffusion or convection
Product configuration	Arterial and venous side ports on filter end caps (ports configured perpendicular to blood flow)	Arterial and venous side ports on filter end caps (ports configured perpendicular to blood flow)
How supplied	Pre-connected to the Streamline Blood Tubing Set with standard Hansen connectors	Pre-connected to the Streamline Blood Tubing Set with standard Hansen connectors
Dialyzer		
Number of fibers	Same	10,900 ± 200
Fiber internal diameter	Same	200 µm
Fiber wall thickness	Same	30 µm
Fiber length	Same	23 cm
Effective surface area	Same	1.6 m^2
Priming volume	Same	91 ml
Max. Transmembrane Pressure	Same	500 mmHg

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In-vitro Performance		
Pressure Drop Blood Compartment (mmHg)	Same	<100 mmHg at Qb=300mL/min UF = 0 ml/min
Pressure Drop Dialysate Compartment (mmHg)	Same	17 mmHg at Qd = 200 ml/min
Ultrafiltration Flow Rates at Specific Blood Flow Rates and TMPs	Same	60 ml/min (Qb 200, TMP 100) 86 ml/min (Qb 200, TMP 300) (Qb in ml/min; TMP in mmHg)
Clearance data (ml/min)		
Urea	Same	50 ml/min at Qb = 100 ml/min Qd = 50 ml/min UF = 0 ml/min
Vitamin B_{12}	Same	44 ml/min at Qb = 100 ml/min Qd = 50 ml/min UF = 0 ml/min[1]
Sieving Coefficients Albumin Urea Creatinine Vitamin B_{12}	Same	 <0.005 1.0 1.0 1.0

NxStage Medical, Inc.
NxStage® Streamline Express
510(k) Premarket Notification Submission

Device Technological Characteristics Comparison Table			
	Proposed Device Streamline Express for Fresenius 2008 Series Hemodialysis Systems	**Predicate Device Streamline Airless System Set with Pre-Attached Dialyzer for B. Braun Dialog Series Hemodialysis Systems (K113023)**	**Predicate Device Blood Tubing Set Streamline Airless System Set with LockSite Needless Access Site (K080807)**
Blood Tubing Set			
Patient connections (Male luer lock)	Same as K113023 & K080807	Yes	Yes
Blood tubing diameters (I.D.)	Same as K113023 & K080807	4.55 - 4.8 mm	4.55 - 4.8 mm
Pump section I.D.	Same as K113023 & K080807	8.0 mm	8.0 mm
Pump segment connectors	Same as K113023 & K080807	Yes	Yes
Heparin line I.D.	Same as K113023 & K080807	0.75 mm	0.75 mm
Saline line	Same as K113023 & K080807	Yes	Yes
Access line	Same as K113023 & K080807	Yes	Yes
Female luer connector	Same as K113023 & K080807	Yes	Yes
Female luer cap	Same as K113023 & K080807	Yes	Yes
Y-Site	Same as K113023 & K080807	Yes	Yes
Needless injection site	Same as K113023 & K080807	Yes	Yes
Clamps	Same as K113023 & K080807	Yes	Yes
Priming volume	201 cc	212 cc	109 – 119 cc
Reverso			
Reverso is cleared as s blood tubing set accessory K994306	The Reverso access flow reversing valve will be included as standard	Available for purchase separately	Available for purchase separately

H. Summary of Non-Clinical Test/Performance Testing - Bench

NxStage believes that the information and data provided in this submission clearly describes the proposed device and demonstrates that the device is adequately designed for the labeled indication for use. Performance, verification and validation testing was conducted following the FDA's Guidance document entitled: *Hemodialysis Blood Tubing Sets - Premarket Notification [510(k)] Submissions* issued on: April 23, 2008 to characterize performance of the proposed device and the predetermined acceptance criteria was met. Results of this testing have documented that the proposed device is substantially equivalent to the predicate devices and is suitable for the labeled indication for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 4, 2014

NxStage Medical, Inc.
Mary Lou Stroumbos
Director, Regulatory Affairs
350 Merrimack Street
Lawrence, MA 01843

Re: K132602
Trade/Device Name: NxStage® Streamline® Express for Fresenius 2008 Series Hemodialysis Systems
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI, FJK, KOC
Dated: December 20, 2013
Received: December 23, 2013

Dear Mary Lou Stroumbos,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132602

Device Name
NxStage® Streamline® Express for Fresenius 2008 Series Hemodialysis Systems

Indications for Use *(Describe)*
The single use dialyzer with pre-attached blood tubing set is indicated for use with the Fresenius 2008 Series Hemodialysis systems for the treatment of acute and chronic renal failure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Herbert P. Lerner -S
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